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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/248,158	02/09/1999	ZHENGYU YUAN	342312000600	8469

7590 03/12/2002  
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EXAMINER

GARCIA, MAURIE E

ART UNIT PAPER NUMBER

1627

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/248,158

Applicant(s)

Yuan et al

Examiner

Maurie E. Garcia, Ph. D.

Art Unit

1627



– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Dec 18, 2001; (10/25/01)
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1, 3, 5-10, 19, and 21-28 is/are pending in the application.
- 4a) Of the above, claim(s) 21-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-10, and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☒ Interview Summary (PTO-413) Paper No(s). 23
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Prosecution Application***

1. The request filed on 10/09/01 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/248,158 is acceptable and a CPA has been established. An action on the CPA follows.
2. The Preliminary Amendment filed 10/25/01 is also acknowledged. Claims 1 and 19 were amended, claim 4 was cancelled and no claims were added.
3. Please note that claims 21-28 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention. Claims 11-18 and 20 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to non-elected species. Election was made without traverse in Paper No. 9.
4. Therefore, claims 1, 3, 5-10 and 19 are examined on the merits in this action.
5. Applicant's Interview Summary (filed October 25, 2001) is correct as to the discussion held on Tuesday October 9, 2001. Additionally, an Interview Summary form for a discussion held December 18, 2001 is attached to this action.

***Withdrawn Rejections***

6. The rejection under 35 U.S.C. 103(a) over Schlenoff is withdrawn in view of applicant's amendments to the claims. Also, the rejection over claim 1 under the second paragraph of 35 U.S.C. 112 denoted "A" is withdrawn in view of applicant's amendments

***Maintained Rejections***  
***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 1 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Withdrawn

B. The terminology "distinct from" in claim 1 is a relative phrase which renders the claim indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Again, the metes and bounds of "distinct from" are unclear (i.e. how is the distinction determined?).

***Response to Arguments***

9. Applicant's arguments filed 10/25/01 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

10. Applicants argues that "distinct from" is definite. However, the examiner maintains that the term is relative, which render the claims indefinite. The question at hand is not what the terms mean in a literal sense but the fact that they are relative terms. This terminology simply does not provide a standard for ascertaining the requisite degree applicant intends. As stated above, the method for determining the distinctness is not set forth. Applicant's discussion of "signal above background" is not found sufficient to completely define this relationship and thus the rejection is maintained.

11. Also, applicant is directed to MPEP 2173.05(a): [t]he meaning of every term used in a claim should be apparent from the prior art or from the specification and drawings at the time the application is filed. Moreover, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

***Maintained Rejections***  
***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

13. Claims 1, 3-10 and 19 remain rejected under 35 U.S.C. 102(e) as being anticipated by Kasila et al (US 5,972,595).

Kasila et al disclose a method for measuring enzyme activity using a solid support coated with a hydrophobic layer (see column 2, lines 10-23). Specifically, the solid supports are 96-well Flashplates<sup>TM</sup> (see definition, column 2, lines 48-50) coated with an artificial lipid layer in various ways (see, for example, column 4, lines 25-38 and column 5, line 63 through column 6, line 22). Enzyme substrates are bound via hydrophobic interactions within the lipid layer (column 3, lines 26-39). The biochemical transformation of the bound substrate causes a cleavage of a portion of the molecule, thus rendering it hydrophilic (see patented claims, especially claim 1). The hydrophilic portion is washed away, thus reducing the level of scintillation (see, for example, column 5, lines 36-60). The assay of Kasila et al can be used to study various enzymes and is designed to study them in high-throughput fashion (column 6, lines 24-60).

***Response to Amendment/Arguments***

14. Applicant's arguments filed 10/25/01 have been fully considered but are not found persuasive. The examiner's rationale is set forth below.

15. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). For example, applicant argues that Kasila does not teach that the reaction product is bound to the scintillating material. As stated in the rejection, Kasila discloses that the "biochemical transformation of the bound substrate causes a cleavage of a portion of the molecule, thus rendering it hydrophilic (see patented claims, especially claim 1)". This chemically transformed substrate can be interpreted as *still bound* to the scintillating material, until the step of washing away this hydrophilic portion, which reduces the level of scintillation (see, for example, column 5, lines 36-60). The instant claims **do not** recite that the binding is permanent.

16. Lastly, the Kasila reference is a U.S. patent that claims the rejected invention (see patented claims 1-8 and 13-18). An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the patent is claiming the same patentable invention, see MPEP § 2306. The patent can only be overcome by establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings.

***New Rejections***  
***Claim Rejections - 35 USC § 112***

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 1, 3, 5-10 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide support for the invention as now claimed. The amended claims now recite that a “reaction product of the chemical or biochemical transformation binds to the scintillating material”. There appears to be insufficient support for this added limitation. In accordance with MPEP § 714.02, applicants **should specifically point out support** for any amendments made to the disclosure. Applicant discusses the added limitations on page 3 (top) of the Response; however this support was found to be very specific in nature (only for a particular example). The examiner’s position is that there is not sufficient support in the instant disclosure for this limitation as *broadly claimed*. There simply is not clear support. The test for sufficiency of support ... is whether the disclosure of the application relied upon “reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.” *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)). The examiner’s position is that the instant disclosure does **not** “reasonably convey to the



artisan that the inventor had possession” of the generic concept of the “reaction product of the chemical or biochemical transformation” binding to the scintillating material.

*Status of Claims/Conclusion*

19. No claims are allowed.
20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie E. Garcia, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday from 9:30 to 7:00 and alternate Fridays.
21. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat, can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie E. Garcia, Ph.D.  
March 11, 2002



**MAURIE E. GARCIA, PH.D.**  
**PATENT EXAMINER**